

§ 26.167

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retesting the aliquot of a single specimen reconfirm any of the original positive, adulterated, or substituted test result(s), the licensee or other entity shall impose the appropriate sanctions specified in subpart D. If the results of testing Bottle B or retesting the aliquot of a single specimen are negative, the licensee or other entity—

(i) May not impose any sanctions on the individual;

(ii) Shall eliminate from the donor's personnel file and other records any matter that could link the individual to the temporary administrative action;

(iii) May not disclose the temporary administrative action in response to a suitable inquiry conducted under the provisions of § 26.63 or to any other inquiry or investigation required in this chapter. To ensure that no records have been retained, access to the system of files and records must be provided to personnel conducting reviews, inquiries into allegations, or audits under the provisions of § 26.41, or to NRC inspectors; and

(iv) Shall provide the tested individual with a written statement that the records specified in §§ 26.713 and 26.715 have not been retained and shall inform the individual in writing that the temporary administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for self-disclosure of potentially disqualifying FFD information.

(2) If a donor requests that Bottle B be tested or that an aliquot of a single specimen be retested, and either Bottle B or the single specimen are not available due to circumstances outside of the donor's control (including, but not limited to, circumstances in which there is an insufficient quantity of the single specimen or the specimen in Bottle B to permit retesting, either Bottle B or the original single specimen is lost in transit to the second HHS-certified laboratory, or Bottle B has been lost at the HHS-certified laboratory or licensee testing facility), the MRO shall cancel the test and inform the licensee or other entity that another collection is required under direct observation as soon as reasonably practical. The licensee or other entity

shall eliminate from the donor's personnel and other records any matter that could link the donor to the original positive, adulterated, or substituted test result(s) and any temporary administrative action, and may not impose any sanctions on the donor for a cancelled test. If test results from the second specimen collected are positive, adulterated, or substituted and the MRO determines that the donor has violated the FFD policy, the licensee or other entity shall impose the appropriate sanctions specified in subpart D of this part, but may not consider the original confirmed positive, adulterated, or substituted test result in determining the appropriate sanctions.

§ 26.167 Quality assurance and quality control.

(a) *Quality assurance program.* Each HHS-certified laboratory shall have a quality assurance program that encompasses all aspects of the testing process, including, but not limited to, specimen accessioning, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrators and controls, and validation of analytical procedures. The performance characteristics (e.g., accuracy, precision, LOD, limit of quantitation (LOQ), specificity) of each test must be validated and documented for each test. Validation of procedures must document that carryover does not affect the donor's specimen results. Periodic re-verification of analytical procedures is required. Quality assurance procedures must be designed, implemented, and reviewed to monitor the conduct of each step of the testing process.

(b) *Calibrators and controls required.* Each analytical run of specimens for which an initial or confirmatory validity test, or an initial or confirmatory drug test, is being performed must include the appropriate calibrators and controls.

(c) *Quality control requirements for performing initial and confirmatory validity tests.* (1) Requirements for performing creatinine tests:

(i) The creatinine concentration must be measured to one decimal place

on both the initial and the confirmatory creatinine tests;

(ii) The initial creatinine test must have a calibrator at 2 mg/dL;

(iii) The initial creatinine test must have a control in the range of 1 to 1.5 mg/dL, a control in the range of 3 to 20 mg/dL, and a control in the range of 21 to 25 mg/dL; and

(iv) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have a calibrator at 2 mg/dL, a control in the range of 1.0 to 1.5 mg/dL, and a control in the range of 3 to 4 mg/dL.

(2) Requirements for performing specific gravity tests:

(i) The refractometer must report and display the specific gravity to four decimal places, and must be interfaced with a laboratory information management system, or computer, and/or generate a hard copy or digital electronic display to document the numerical result;

(ii) The initial and confirmatory specific gravity tests must have a calibrator or control at 1.0000; and

(iii) The initial and confirmatory specific gravity tests must have the following controls:

(A) One control targeted at 1.0020;

(B) One control in the range of 1.0040 to 1.0180; and

(C) One control equal to or greater than 1.0200 but not greater than 1.0250.

(3) Requirements for performing pH tests:

(i) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Dipsticks, colorimetric pH tests, and pH paper that have a narrow dynamic range and do not support the 2 to 12 pH cutoffs may be used only to determine whether initial validity tests must be performed;

(ii) At a minimum, pH screening tests must have the following controls:

(A) One control below the lower decision point in use;

(B) One control between the decision points in use; and

(C) One control above the upper decision point in use;

(iii) If a pH screening test is not used, an initial pH meter test must have the following calibrators and controls:

(A) One calibrator at 4;

(B) One calibrator at 7;

(C) One calibrator at 10;

(D) One control in the range of 2 to 2.8;

(E) One control in the range of 3.2 to 4;

(F) One control in the range of 10 to 10.8; and

(G) One control in the range of 11.2 to 12;

(iv) If a pH screening test is used, an initial or confirmatory pH meter test must have the following calibrators and controls when the screening result indicates that the pH is below the lower decision point in use:

(A) One calibrator at 4;

(B) One calibrator at 7;

(C) One control in the range of 2 to 2.8; and

(D) One control in the range of 3.2 to 4;

(v) If a pH screening test is used, an initial or confirmatory pH meter test must have the following calibrators and controls when the screening result indicates that the pH is above the upper decision point in use:

(A) One calibrator at 7;

(B) One calibrator at 10;

(C) One control in the range of 10 to 10.8; and

(D) One control in the range of 11.2 to 12; and

(vi) An initial colorimetric pH test must have the following calibrators and controls:

(A) One calibrator at 3;

(B) One calibrator at 11;

(C) One control in the range of 2 to 2.8;

(D) One control in the range of 3.2 to 4;

(E) One control in the range of 4.5 to 9;

(F) One control in the range of 10 to 10.8;

(G) One control in the range of 11.2 to 12.

(4) Requirements for performing oxidizing adulterant tests:

(i) Initial tests for oxidizing adulterants must include a calibrator at the appropriate cutoff concentration

for the compound of interest as specified in § 26.161(c) and (f), a control without the compound of interest (i.e., a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration; and

(ii) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory analytical run must include a calibrator at the appropriate cutoff concentration for the compound of interest as specified in § 26.161(c) and (f), a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

(5) Requirements for performing nitrite tests: The initial and confirmatory nitrite tests must have a calibrator at the cutoff concentration, a control without nitrite (i.e., certified negative urine specimen), one control in the range of 200 to 400 mcg/mL, and one control in the range of 500 to 625 mcg/mL.

(6) Requirements for performing “other” adulterant tests:

(i) The initial and confirmatory tests for any “other” adulterant that may be identified in the future must satisfy the requirements in § 26.161(a);

(ii) The confirmatory test for “other” adulterants must use a different analytical principle or chemical reaction than that used for the initial test; and

(iii) The initial and confirmatory tests for “other” adulterants must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

(d) *Quality control requirements for performing initial drug tests.* (1) Any initial drug test performed by an HHS-certified laboratory must use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. Non-instrumented immunoassay testing devices that are pending HHS/SAMHSA review and approval may not be used for initial drug testing under this part.

(2) HHS-certified laboratories may perform multiple initial drug tests for the same drug or drug class, provided that all tests meet the cutoffs and quality control requirements of this part. For example, an HHS-certified laboratory may use immunoassay technique “A” for all drugs using the licensee’s or other entity’s cutoff levels, but specimens testing positive for amphetamines may also be tested using immunoassay technique “B” to eliminate any possible positives due to structural analogues; or, a valid analytical result cannot be obtained using immunoassay technique “A” and immunoassay technique “B” is used in an attempt to obtain a valid analytical result.

(3) Quality control samples for each analytical run of specimens for initial testing must include—

(i) Sample(s) certified to contain no drugs or drug metabolites (i.e., negative urine samples);

(ii) At least one positive control with a drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff;

(iii) At least one positive control with a drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff;

(iv) A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff (after acceptable values are obtained for the known calibrators, those values will be used to calculate sample data); and

(v) At least one control that appears to be a donor specimen to the laboratory analysts.

(4) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples, as defined by paragraphs (d)(3)(i) through (iv) of this section.

(e) *Quality control requirements for performing confirmatory drug tests.* (1) Confirmatory tests for drugs and drug metabolites must be performed using gas chromatography/mass spectrometry (GC/MS) or other confirmatory test methodologies that HHS-certified laboratories are permitted to use in Federal workplace drug testing programs for this purpose.

(2) At least 10 percent of the samples in each analytical run of specimens must be calibrators and controls.

(3) Each analytical run of specimens that are subjected to confirmatory testing must include—

(i) Sample(s) certified to contain no drug (i.e., negative urine samples);

(ii) Positive calibrator(s) and control(s) with a drug(s) or drug metabolite(s);

(iii) At least one positive control with a drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff; and

(iv) At least one calibrator or control that is targeted at or below 40 percent of the cutoff.

(f) *Errors in testing.* The licensee or other entity shall ensure that the HHS-certified laboratory investigates any testing errors or unsatisfactory performance discovered in blind performance testing, as required under § 26.168, in the testing of actual specimens, or through the processing of reviews, as well as any other errors or matters that could adversely reflect on the testing process.

(1) Whenever possible, the investigation must determine relevant facts and identify the root cause(s) of the testing or process error. The licensee or other entity, and the HHS-certified laboratory, shall take action to correct the causes of any errors or unsatisfactory performance that are within each entity's control. Sufficient records shall be maintained to furnish evidence of activities affecting quality. The licensee or other entity shall assure that the cause of the condition is determined and that corrective action is taken to preclude repetition. The identification of the significant condition, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

(2) If a false positive error occurs on a blind performance test sample or on a regular specimen, the licensee or other entity shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future. If there is reason to believe that the error could have been systematic, the licensee or other entity

may also require review and re-analysis of previously run specimens.

(3) If a false positive error occurs on a blind performance test sample and the error is determined to be technical or methodological, the licensee or other entity shall instruct the laboratory to provide all quality control data from the batch or analytical run of specimens that included a false positive sample. In addition, the licensee or other entity shall require the laboratory to retest all specimens that analyzed as positive for that drug or metabolite, or as adulterated, substituted, dilute, or invalid in validity testing, from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting must be documented by a statement signed by the laboratory's responsible person. The licensee or other entity and the NRC also may require an onsite review of the laboratory, which may be conducted unannounced during any hours of operation of the laboratory.

(g) *Accuracy.* Volumetric pipettes and measuring devices must be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedures. Automatic pipettes and dilutors must be checked for accuracy and reproducibility both before being placed in service and periodically thereafter.

(h) *Calibrators and controls.* Laboratory calibrators and controls must be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions that are obtained from commercial manufacturers and are properly labeled as to content and concentration. Calibrators and controls may not be prepared from the same stock solution. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and when scheduled for expiration.

§ 26.168 Blind performance testing.

(a) Each licensee and other entity shall submit blind performance test samples to the HHS-certified laboratory.

(1) During the initial 90-day period of any contract with an HHS-certified